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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,644	SILVERBERG ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of amendment, filed 09/13/2007.

Claims 1-21 have been pending, claim 8 has been canceled and claim 22 has been added.

Claims 1-7, 9-22 are pending and included in the prosecution.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,491,070 ('070).

The present claim is interpreted as require polymer prepared from monomer selected form the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers **and/or** alkyl methacrylate monomers. The claims require therapeutic agent.

US '070 disclosed excellent pressure sensitive adhesive with good tack obtained by the combination of monomers to form polymers consisting of 80-96% of 2-ethylhexyl acrylate and 2.0-19% of octyl acrylamide to create a polymer combination that is synergistic in nature (col.1, lines 52-60). The Tg as claimed by claim 4 is inherent for specific polymer. The pressure sensitive adhesive further comprises ammonium persulfate that is known as antimicrobial agent as evident by US 5,827,505, which reads on therapeutic agent.

Response to Arguments

3. Applicant's arguments filed 09/13/2007 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that US '070 (Weaver) requires methylacrylamide monomer as essential component. US '070 to teach the acrylic polymer required for use in the practice of applicants' invention as one lacking functional groups containing reactive hydrogen. No disclosure in US '070 of an adhesive that contains a therapeutic agent as required in the practice of applicants' invention.

In response to these argument, applicants' attention is drawn to the "comprising" language of the present claims that does not exclude other elements or materials even in major amounts. *Cues Inc. vs. Polymer Industries*, USPQ 2d 1847 (DC ND GA 1988);

Moleculon Research Corporation v CBS, Inc. 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. Therefore the claims' language permits methylacrylamide monomer, and even methylacrylamide monomer is claimed by claim 6. Therefore, methylacrylamide monomer disclosed by the reference is within the scope of the present claims as an essential element that is a nitrogen-containing monomer.

Regarding the argument that the reference does not teach monomer lacking functional groups containing reactive hydrogen, it is argued that US '070 teaches the same adhesive composition having the same components as instantly claimed and inherently the monomer are lacking functional groups containing nitrogen.

With regard to active agent, US '070 disclosed that the pressure sensitive adhesive comprises ammonium persulfate that is known as antimicrobial agent as evident by US 5,827,505, which reads on therapeutic agent. The present invention is directed to composition, and all the elements of the composition are disclosed by the reference.

4. Claims 1-6, 9-14 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 531 938 ('938).

The present claim is interpreted as require polymer prepared from monomer selected form the group consisting of monomers selected from the group consisting of: alkyl acrylate, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer. Further the claims require 50-98% alkyl acrylate monomers **and/or** alkyl methacrylate monomers. The claims require therapeutic agent.

EP '938 disclosed medical preparation for percutaneous absorption of drugs (abstract). The preparation is applied on a substrate, i.e. backing (page 3, lines 14-20).

The preparation comprises pressure sensitive acrylic based layer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate (page 4, lines 13-19). The alkyl (meth)acrylate is ethylhexyl acrylate (page 4, lines 21-22; example1). The monomer copolymerizable with the alkyl (meth)acrylate includes (meth)acrylmide, meeting claim 6, and (meth)acrylonitrile, meeting claim 3 (page 4, lines 29, 36). The drugs included in the adhesive layer include analgesics, hypnotics and sedatives (page 6, lines 15-21). The Tg as claimed by claim 4 is inherent for specific polymer.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 7 are rejected under 35 U.S.C. 103(a) as being obvious over '938 in view of US '070.

The teachings of EP '938 and US '070 are discussed under 102 rejections as set forth in this office action.

Although EP '938 teaches methacrylamide, however, the reference does not explicitly teach octyl acrylamide claimed in claims 7, which is taught by US '070 to have a good tack when combined with 2-ethylhexyl acrylate to create a polymer combination that is synergistic in nature.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide monomer as disclosed by EP '938, and replace the acrylamide monomer with octyl acrylamide disclosed by US '070, motivated by the teaching of US '070 that the combination of alkyl (meth)acrylate and octyl acrylamide has a good tack and creates a polymer combination that is synergistic in nature, with reasonable expectation of having polymer adhesive composition obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and octyl acrylamide that has good tack and synergistic adhesive nature.

8. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '938 in view of US 6,139,866 ('866).

The teachings of EP '938 are discussed under 102 rejections as set forth in this office action.

Although EP '938 teaches analgesics, sedatives and hypnotic drugs to be delivered by the disclosed adhesive, however, the reference does not explicitly teach fentanyl as claimed by claims 15-17.

US '866 teaches suitability of fentanyl to be administered transdermally with little skin irritation and its ability to provide prolonged analgesic or anesthetic effect (abstract; col.1, lines 15-17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide monomer to deliver analgesic, hypnotic or sedative as disclosed by EP '938, and replace the analgesic, sedative or hypnotic drug with fentanyl that is taught by US '866 as being suitable for transdermal administered with little skin irritation and prolonged analgesic or anesthetic effect, with reasonable expectation of having fentanyl successfully delivered from polymer adhesive composition obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide without skin irritation and with prolonged analgesic or anesthetic effect.

9. Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '938 in view of US 5,458,885 ('885).

The teachings of EP '938 are discussed under 102 rejections as set forth in this office action.

Although EP '938 teaches two or more alkyl (meth)acrylate in the polymer, however, the reference does not explicitly teach 2-ethylhexyl acrylate and methyl acrylate as required by claims 18 and 20.

US '885 teaches transdermal system comprising polymer made of methyl acrylate and 2-ethylhexyl acrylate wherein the polymer is suitable to deliver basic active agents and their salts including analgesics (col.2, lines 43-55; col.3, lines 3-9, 64-67; col.4, lines 1-50; col.6, lines 37, 50-60; col.7, lines 1-9).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide monomer as disclosed by EP '938, and replace the acrylate monomer with methyl acrylate and 2-ethylhexyl acrylate as disclosed by US '885, motivated by the teaching of US '885 that such a polymer is suitable to deliver basic active agents and their salts including analgesics, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate and acrylamide monomer wherein the polymer provides successful delivery to basic therapeutic agents including analgesics.

10. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '938 in view of US '885 and further in view of US '070.

The combined teaching of EP '938 and US '885 are discussed as set forth in this office action.

However, the combined teaching of the EP '938 and US '885 does not teach octyl-acrylamide that is taught by US '070 to have a good tack when combined with 2-ethylhexyl acrylate to create a polymer combination that is synergistic in nature.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate and acrylamide monomer as taught by the combined teaching of EP '938 and US '885, and replace the acrylamide with octyl acrylamide as taught by US '070, motivated by the teaching of US '070 that the combination of alkyl acrylate and octyl acrylamide has a good tack and creates a polymer combination that is synergistic in nature, with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer comprising 2-ethylhexyl acrylate and methyl acrylate, and octyl acrylamide monomer that has good tack and synergistic adhesive nature.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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